IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	)	C.A. No. 22-252-MSG
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	)	

PLAINTIFFS ARBUTUS BIOPHARMA CORPORATION AND GENEVANT SCIENCES GMBH'S ANSWER TO DEFENDANTS MODERNA, INC. AND MODERNATX, INC.'S COUNTERCLAIMS

Plaintiffs/Counterclaim-Defendants Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs"), by their attorneys, answer the counterclaims of Defendants/Counterclaim-Plaintiffs Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") as follows. This Answer reproduces Defendants' counterclaims followed by Plaintiffs' responses.

INTRODUCTION

1. Moderna brings these counterclaims in response to Arbutus and Genevant's lawsuit, which baselessly seeks to profit from Moderna's innovations that led to its ground-breaking mRNA-1273 "COVID-19 Vaccine." Specifically, Moderna asks this Court to declare that Moderna's COVID-19 Vaccine does not infringe the Asserted Patents, and that those patents

are invalid. In short, this lawsuit will confirm that Moderna and its scientists, employees, and collaborators are the true innovators in the mRNA delivery technology that led to its lifesaving COVID-19 Vaccine. Plaintiffs played no role in Moderna's significant accomplishments.

ANSWER: The allegations of Paragraph 1 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that they filed a Complaint against Moderna on February 28, 2022, and an Amended Complaint against Moderna on May 1, 2024. Otherwise, **DENIED**.

2. For a decade before COVID-19 emerged, Moderna had been pioneering a new class of medicines made of messenger RNA, or mRNA, and developed its own platform technologies that could deliver mRNA in a variety of therapeutic and prophylactic applications, including vaccines. These mRNA medicines have the potential to treat and prevent a wide range of diseases—from infectious diseases like influenza and HIV, to autoimmune and cardiovascular diseases and rare forms of cancer. Over the past twelve years, Moderna has worked diligently in its laboratories to pioneer a number of fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines—from the characteristics and design of the mRNA itself and the protein it encodes, to the technologies to deliver mRNA to patients safely and effectively.

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief about the allegations in Paragraph 2, and therefore **DENY** them.

3. Included among the mRNA advancements that Moderna developed over years of extensive work, is its proprietary lipid nanoparticle ("LNP") delivery technologies to encapsulate the mRNA for delivery. The LNPs function to protect the mRNA and deliver it into cells.

ANSWER: Plaintiffs **ADMIT** that lipid nanoparticles ("LNPs") can function to protect mRNA and deliver it into cells. Plaintiffs lack knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 3, and therefore **DENY** them.

4. Moderna invested years of work and resources to develop LNPs that are tailored to work with mRNA. Those efforts included developing novel proprietary lipids and optimal lipid compositions, and improving LNP manufacturing processes. Moderna's inventions in this area have been recognized with multiple U.S. patents.

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 and therefore **DENY** them.

5. Moderna's innovative proprietary LNP formulation technology, developed to address the complex problem of reliably delivering mRNA to a patient, goes well beyond the rudimentary, early technology for delivery of siRNA described in Arbutus's Asserted Patents, nor is it covered by those patents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 5.

6. In contrast to Moderna's proprietary LNP technology to deliver mRNA, Arbutus (and its predecessor Protiva Biotherapeutics, Inc., "Protiva") conducted research relating to delivery of small interfering RNA ("siRNA"), small pieces of RNA "about 15–60 . . . nucleotides in length" as defined by Arbutus. *See, e.g.*, U.S. Patent No. 8,058,069 ("'069 Patent") at 6:55–66. siRNA is a far cry from the long, complex mRNA that Moderna's technology is designed to deliver. By way of example, Moderna's COVID-19 Vaccine delivers mRNA that is approximately 4,000 nucleotides—over 60 times the length contemplated by the Arbutus patents.

ANSWER: Plaintiffs **ADMIT** that some research conducted by Arbutus and Protiva included work on siRNA. Plaintiffs **ADMIT** that U.S. Patent No. 8,058,069 ("'069 Patent") includes the following statement: "Interfering RNA includes 'small-interfering RNA' or 'siRNA,' e.g., interfering RNA of about 15-60, 15-50, or 15-40 (duplex) nucleotides in length, more typically about 15-30, 15-25, or 19-25 (duplex) nucleotides in length, and is preferably about 20-24, 21-22, or 21-23 (duplex) nucleotides in length . . . ." '069 Patent at 6:55–60. Plaintiffs **DENY** the remaining allegations in Paragraph 6.

7. None of the Asserted Patents focus on mRNA. For example, the specification of the '069 Patent (and related Asserted Patents) focuses on siRNA, not mRNA, discussing "Selection of siRNA Sequences," "Generating siRNA Molecules," "Modifying siRNA Sequences," and "Target Genes" of siRNA. *See, e.g.*, '069 Patent at cols. 29, 32, 33, and 35. Indeed, all 11 examples of the '069 Patent (and its asserted family members) are directed to "nucleic acid-lipid particles" comprising siRNA—none involve mRNA. *Id.* at 67:64–86:18; *see also* U.S. Patent 9,504,651 at cols. 14–19 (Examples 1–8, none of which are directed to mRNA formulations). This is consistent with Arbutus predecessor Protiva's public statements at the time that the company was "focused on" "formulations for RNAi therapeutics." As another example, the '651 Patent focuses on plasmid DNA, rather than mRNA. *See* '651 Patent at 2:17–19 ("The present invention can be used to form lipid vesicles that contain encapsulated plasmid DNA or small molecule drugs."), and cols. 14–15.

ANSWER: Plaintiffs **ADMIT** that the '069 Patent contains headings titled "Selection of siRNA Sequences," "Generating siRNA Molecules," "Modifying siRNA Sequences," and

"Target Genes." '069 Patent at cols. 29, 32, 33, and 35. Plaintiffs **ADMIT** that the website cited by Defendants states that "Tekmira and Protiva each have liposome formulations suitable for a range of nucleic acid-based drugs, although both are focused on and have several formulations for RNAi therapeutics. Protiva's liposomal platform is called SNALP (for stable nucleic acid-lipid particles)." Plaintiffs **ADMIT** that the '651 Patent states that "[t]he present invention can be used to form lipid vesicles that contain encapsulated plasmid DNA or small molecule drugs." Otherwise, **DENIED.**

8. Tellingly, Plaintiffs/Counterclaim Defendants never developed an LNP capable of delivering mRNA, let alone manufactured or sold any approved products of their own, whether siRNA or mRNA-based.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 8.

9. Failing to develop any products of its own, Arbutus instead improperly expanded the scope of its patent estate in an attempt to cover the inventions of others, including pioneers like Moderna. Consequently, the purported inventions that Arbutus lays claim to in the Asserted Patents bear no resemblance to the rudimentary technology described in the specifications.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 9.

10. The SARS-CoV2 virus, which causes COVID-19, was first detected in December 2019. On January 10, 2020, the genetic sequence of the SARS-CoV-2 virus became public. Leveraging its decade of research and proprietary technologies, Moderna quickly responded when the pandemic struck, swiftly developing, manufacturing, and providing doses of its COVID-19 vaccine to people around the world. The COVID-19 Vaccine, also referred to as the mRNA-1273 vaccine, uses Moderna's proprietary LNP delivery technology that Moderna developed and described years earlier. For that groundbreaking work, Moderna's scientists were recently honored by the American Chemistry Society's 2022 Heroes of Chemistry Award, the highest honor for industrial chemical scientists, recognizing their "work developing formulations that protect against . . . COVID-19."

ANSWER: Plaintiffs **ADMIT** that the SARS-CoV2 virus, which causes COVID-19, was first detected in December 2019. Plaintiffs **ADMIT** that on January 10, 2020, the genetic sequence of the SARS-CoV-2 virus became public. Plaintiffs lack knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 and therefore **DENY** them.

11. Following the declaration of a public health emergency, Moderna entered into numerous agreements with the U.S. Government regarding its COVID-19 Vaccine. In April 2020, Moderna entered into a grant agreement with the Biomedical Advanced Research and Development Authority ("BARDA")—an office of HHS—to support clinical development of the mRNA-1273 vaccine. BARDA chose to partner with Moderna to develop the COVID-19 vaccine because "Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus."

ANSWER: Plaintiffs **ADMIT** that the COVID-19 pandemic was declared a public health emergency. Plaintiffs **ADMIT** that the document cited by Defendants states that "Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus." Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11 and therefore **DENY** them.

12. Once Moderna had obtained promising clinical results, on August 9, 2020, ModernaTX, Inc. entered into a supply contract with the Army Contracting Command of the U.S. Department of Defense, Contract No. W911QY20C0100 ("C0100 Contract"). Under the C0100 Contract, Moderna was obligated to produce and deliver doses of its COVID-19 Vaccine to the U.S. Government, with the option to supply additional doses. The C0100 Contract specifically states that Moderna manufactured the COVID-19 Vaccine doses "for the United States Government." The C0100 contract also incorporates by reference FAR 52.227-1, entitled "Authorization and Consent," and FAR 52.227-1 Alt 1, entitled "Authorization And Consent (JUN 2020) - Alternate I."

ANSWER: On information and belief, Plaintiffs **ADMIT** that the document cited by Defendants, D.I. 17-1, Ex. A, is listed as "Contract No. W911QY20C0100" with an Effective Date listed as August 9, 2020. D.I. 17-1, Ex. A at 1. Plaintiffs **ADMIT** that ModernaTX, Inc. is listed as the contractor on the document cited by Defendants, and the contract states that it is administered by the Defense Contract Management Agency of Boston, MA. *Id*. Plaintiffs

ADMIT that the document cited by Defendants states that "The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population." *Id*. at 19. Plaintiffs **ADMIT** that the document cited by Defendants contains a list of "CLAUSES INCORPORATED BY REFERENCE," and contained in this list is 52.227-1, titled "Authorization and Consent" and dated June 2020, and 52.227-1 Alt I, titled "Authorization And Consent (JUN 2020) – Alternate I" dated April 1984. *Id*. at 46. Plaintiffs lack knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 12, and therefore **DENY** them.

13. Moderna received unprecedented emergency use authorization for its COVID-19 Vaccine in the U.S. from the Food & Drug Administration ("FDA") on December 16, 2020—within less than a year of beginning development. Promptly thereafter, Moderna shipped U.S.-manufactured COVID-19 Vaccine doses to the U.S. Government pursuant to the C0100 Contract. Moderna also supplied foreign governments with doses of the COVID-19 Vaccine. On January 31, 2022, Moderna received full approval from the FDA for its Biologics License Application for the COVID-19 Vaccine.

ANSWER: Plaintiffs **ADMIT** that on January 31, 2022, the FDA approved Moderna's Biologics License Application ("BLA") for its COVID-19 vaccine. Upon information and belief, Plaintiffs **ADMIT** that Moderna supplied foreign governments with doses of its COVID-19 vaccine. Plaintiffs **DENY** that Moderna received emergency use authorization for its COVID-19 vaccine in the U.S. from the FDA on December 16, 2020. Plaintiffs lack knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 13, and therefore **DENY** them.

PARTIES

14. Moderna, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139.

ANSWER: On information and belief, Plaintiffs **ADMIT** the allegations of Paragraph 14.

15. ModernaTX, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139.

ANSWER: On information and belief, Plaintiffs **ADMIT** the allegations of Paragraph 15.

16. Upon information and belief, Plaintiff/Counterclaim-Defendant Arbutus Biopharma Corporation is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974.

ANSWER: Plaintiffs **ADMIT** the allegations of Paragraph 16.

17. Upon information and belief, Plaintiff/Counterclaim-Defendant Genevant Sciences GmbH is a company organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland.

ANSWER: Plaintiffs **ADMIT** the allegations of Paragraph 17.

NATURE OF ACTION

18. Moderna seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., that U.S. Patent Nos. 8,058,069 (the "'069 Patent"), 8,492,359 (the "'359 Patent"), 8,822,668 (the "'668 Patent"), 9,364,435 (the "'435 Patent"), 9,504,651 (the "'651 Patent"), and 11,141,378 (the"'378 Patent") (collectively, "Asserted Patents") are invalid and/or not infringed.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Plaintiffs **ADMIT** that Moderna's counterclaims against Plaintiffs seek declaratory judgment that U.S. Patent Nos. 8,058,069 (the "'069 Patent"), 8,492,359 (the "'359 Patent"), 8,822,668 (the "'668 Patent"), 9,364,435 (the "'435 Patent"), 9,504,651 (the "'651 Patent"), and 11,141,378 (the"'378 Patent") (collectively, "Asserted Patents") are invalid and/or not infringed. To the extent there are allegations not expressly admitted above, such allegations are **DENIED**.

JURISDICTION AND VENUE

19. This Court has exclusive subject matter jurisdiction over this action pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338; and the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

ANSWER: The allegations of Paragraph 19 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has subject matter jurisdiction over this action.

20. This Court has personal jurisdiction over Arbutus and Genevant because each has subjected itself to the jurisdiction of this Court by filing the Amended Complaint.

ANSWER: The allegations of Paragraph 20 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that they filed the Amended Complaint and do not contest that they are subject to personal jurisdiction for purposes of this action.

21. Venue in this Court is proper based on the choice of forum by Plaintiffs and pursuant to 28 U.S.C. §§ 1391(b)-(c), and 1400(b).

ANSWER: The allegations of Paragraph 21 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this District is a proper venue for this action.

FACTUAL BACKGROUND

22. On or about November 15, 2011, the ’069 Patent was issued to Protiva Biotherapeutics, Inc.

ANSWER: Plaintiffs **ADMIT** that the ’069 Patent was issued to Protiva Biotherapeutics, Inc. on November 15, 2011.

23. On or about July 23, 2013, the ’359 Patent was issued to Protiva Biotherapeutics, Inc.

ANSWER: Plaintiffs **ADMIT** that the '359 Patent was issued to Protiva Biotherapeutics, Inc. on July 23, 2013.

24. On or about September 2, 2014, the '668 Patent was issued to Protiva Biotherapeutics, Inc.

ANSWER: Plaintiffs **ADMIT** that the '668 Patent was issued to Protiva Biotherapeutics, Inc. on September 2, 2014.

25. On or about June 14, 2016, the '435 Patent was issued to Protiva Biotherapeutics, Inc.

ANSWER: Plaintiffs **ADMIT** that the '435 Patent was issued to Protiva Biotherapeutics, Inc. on June 14, 2016.

26. On or about November 29, 2016, the '651 Patent was issued to Protiva Biotherapeutics, Inc.

ANSWER: Plaintiffs **ADMIT** that the '651 Patent was issued to Protiva Biotherapeutics, Inc. on November 29, 2016.

27. On or about October 12, 2021, the '378 Patent was issued to Arbutus Biopharma Corporation.

ANSWER: Plaintiffs **ADMIT** that the '378 Patent was issued to Arbutus Biopharma Corporation on October 12, 2021.

28. Arbutus purports to be the owner and assignee of all Asserted Patents.

ANSWER: Plaintiffs **ADMIT** that all Asserted Patents are assigned to and owned by Arbutus.

29. Genevant purports to be the exclusive licensee to all Asserted Patents.

ANSWER: Plaintiffs **ADMIT** that at all times since Arbutus and Genevant entered into a license agreement, Genevant has held Exclusive Rights (as defined in the Complaint, D.I.

1 at Paragraph 9) to all of the Asserted Patents in certain fields of use, including the vaccine application at issue here.

30. On February 28, 2022, Plaintiffs Arbutus and Genevant filed a lawsuit against Moderna asserting that Moderna's COVID-19 Vaccine infringes the Asserted Patents.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022 and respectfully refer the Court to the Complaint for its actual language and complete content.

31. Pursuant to 28 U.S.C. § 2201(a), an actual and justiciable controversy has arisen and exists between Moderna and Plaintiffs. Moderna is entitled to a judicial determination and declaration that it has not infringed and is not infringing the Asserted Patents, and that the Asserted Patents are invalid.

ANSWER: The allegations of Paragraph 31 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the Asserted Patents.

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '069 PATENT

32. Moderna repeats and incorporates paragraphs 1-31 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-31 as if fully set forth herein.

33. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '069 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and Amended Complaint for their actual language and complete content.

34. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '069 Patent.

ANSWER: The allegations of Paragraph 34 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the '069 Patent.

35. Moderna has not infringed and is not infringing any valid claim of the '069 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '069 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '069 Patent depend from claim 1.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 35.

36. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '069 Patent, either literally or under the doctrine of equivalents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 36.

COUNT II: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '359 PATENT

37. Moderna repeats and incorporates paragraphs 1-36 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-36 as if fully set forth herein.

38. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '359 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and Amended Complaint for their actual language and complete content.

39. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '359 Patent.

ANSWER: The allegations of Paragraph 39 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the '359 Patent.

40. Moderna has not infringed and is not infringing any valid claim of the '359 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '359 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '359 Patent depend from claim 1.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 40.

41. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '359 Patent, either literally or under the doctrine of equivalents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 41.

COUNT III: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '668 PATENT

42. Moderna repeats and incorporates paragraphs 1-41 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-41 as if fully set forth herein.

43. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '668 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

44. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '668 Patent.

ANSWER: The allegations of Paragraph 44 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the '668 Patent.

45. Moderna has not infringed and is not infringing any valid claim of the '668 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '668 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '668 Patent depend from claim 1.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 45.

46. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '668 Patent, either literally or under the doctrine of equivalents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 46.

COUNT IV: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '435 PATENT

47. Moderna repeats and incorporates paragraphs 1-46 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-46 as if fully set forth herein.

48. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '435 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

49. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '435 Patent.

ANSWER: The allegations of Paragraph 49 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the '435 Patent.

50. Moderna has not infringed and is not infringing any valid claim of the '435 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of at least claim 7 of the '435 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '435 Patent depend from claim 1.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 50.

51. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '435 Patent, either literally or under the doctrine of equivalents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 51.

COUNT V: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '651 PATENT

52. Moderna repeats and incorporates paragraphs 1-51 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-51 as if fully set forth herein.

53. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '651 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

54. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '651 Patent.

ANSWER: The allegations of Paragraph 54 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the '651 Patent.

55. Moderna has not infringed and is not infringing any valid claim of the '651 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '651 Patent at least because it does not comprise the claimed "lipid vesicles . . . wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles," and all dependent claims of the '651 Patent depend from claim 1.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 55.

56. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '651 Patent, either literally or under the doctrine of equivalents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 56.

COUNT VI: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '378 PATENT

57. Moderna repeats and incorporates paragraphs 1-56 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-56 as if fully set forth herein.

58. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '378 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

59. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '378 Patent.

ANSWER: The allegations of Paragraph 59 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there is a case of actual controversy between Plaintiffs on the one hand and Moderna on the other regarding Moderna's infringement, active inducement of infringement, and contribution to the infringement by others of the '378 Patent.

60. Moderna has not infringed and is not infringing any valid claim of the '378 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '378 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "polyethyleneglycol (PEG)-lipid conjugate") in the claimed ratios, and all dependent claims of the '378 Patent depend from claim 1.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 60.

61. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '378 Patent, either literally or under the doctrine of equivalents.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 61.

COUNT VII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '069 PATENT

62. Moderna repeats and incorporates paragraphs 1-61 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-61 as if fully set forth herein.

63. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '069 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

64. Moderna alleges that the claims of the '069 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '069 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 64.

65. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 65.

66. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, *inter alia*, the validity of the claims of the '069 Patent.

ANSWER: The allegations of Paragraph 66 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there exists an actual controversy between Moderna on the one hand and Plaintiffs on the other hand as to whether the claims of the '069 Patent are valid.

67. Moderna is entitled to a declaration that one or more claims of the '069 Patent are invalid.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 67.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '359 PATENT

68. Moderna repeats and incorporates paragraphs 1-67 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-67 as if fully set forth herein.

69. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '359 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

70. Moderna alleges that the claims of the '359 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '359 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 70.

71. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 71.

72. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '359 Patent.

ANSWER: The allegations of Paragraph 72 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there exists an actual controversy between Moderna on the one hand and Plaintiffs on the other hand as to whether the claims of the '359 Patent are valid.

73. Moderna is entitled to a declaration that one or more claims of the '359 Patent are invalid.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 73.

COUNT IX: DECLARATORY JUDGMENT OF INVALIDITY OF THE '668 PATENT

74. Moderna repeats and incorporates paragraphs 1-73 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-73 as if fully set forth herein.

75. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '668 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

76. Moderna alleges that the claims of the '668 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '668 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 76.

77. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 77.

78. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '668 Patent.

ANSWER: The allegations of Paragraph 78 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there exists

an actual controversy between Moderna on the one hand and Plaintiffs on the other hand as to whether the claims of the '668 Patent are valid.

79. Moderna is entitled to a declaration that one or more claims of the '668 Patent are invalid.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 79.

COUNT X: DECLARATORY JUDGMENT OF INVALIDITY OF THE '435 PATENT

80. Moderna repeats and incorporates paragraphs 1-79 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-79 as if fully set forth herein.

81. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '435 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

82. Moderna alleges that the claims of the '435 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '435 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 82.

83. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 83.

84. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '435 Patent.

ANSWER: The allegations of Paragraph 84 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there exists an actual controversy between Moderna on the one hand and Plaintiffs on the other hand as to whether the claims of the '435 Patent are valid.

85. Moderna is entitled to a declaration that one or more claims of the '435 Patent are invalid.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 85.

COUNT XI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '651 PATENT

86. Moderna repeats and incorporates paragraphs 1-85 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-85 as if fully set forth herein.

87. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '651 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

88. Moderna alleges that the claims of the '651 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 6,841,537 or U.S. 6,734,171, and the claims of the '651 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Further, claim 1 is anticipated or obvious in light of prior art references including, but not limited to, U.S. Patent No. 6,271,208, U.S. Patent No. 6,110,745, WO 01/11068 A2, WO 01/15726 A2, WO 98/51278, and Saravolac 2000.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 88.

89. In addition, the specification fails to describe or enable, for example, the claimed "lipid vesicles" in claim 1 with the recited broad genus of "cationic lipid," "amphipathic lipid" and "polyethyleneglycol (PEG)-lipid," wherein "at least 70% of the mRNA in the formulation is fully encapsulated" as claimed. As another example, claim 1 recites compositions comprising "messenger RNA (mRNA)," but the specification fails to describe or enable any examples of "lipid vesicles" comprising mRNA, let alone those wherein "at least 70% of the mRNA in the formulation is fully encapsulated" as claimed.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 89.

90. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, *inter alia*, the validity of the claims of the '651 Patent.

ANSWER: The allegations of Paragraph 90 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there exists an actual controversy between Moderna on the one hand and Plaintiffs on the other hand as to whether the claims of the '651 Patent are valid.

91. Moderna is entitled to a declaration that one or more claims of the '651 Patent are invalid.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 91.

COUNT XII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '378 PATENT

92. Moderna repeats and incorporates paragraphs 1-91 as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to Paragraphs 1-91 as if fully set forth herein.

93. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '378 Patent.

ANSWER: Plaintiffs **ADMIT** that they filed the Complaint on February 28, 2022, and the Amended Complaint on May 1, 2024, and respectfully refer the Court to the Complaint and the Amended Complaint for their actual language and complete content.

94. Moderna alleges that the claims of the '378 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without

limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, claim 1 is anticipated or obvious in light of prior art references including, but not limited to, Zimmerman 2006, Thomas 2007, and U.S. Patent Pub. No. 2008/0020058 A1. Further, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, and the claims of the '378 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 94.

95. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "mixture of a phospholipid and cholesterol" and "polyethyleneglycol (PEG)-lipid conjugate." As another example, claim 1 recites compositions comprising the broad genus of "RNA," but, other than siRNA, the specification fails to describe or enable any examples of RNA including mRNA.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 95.

96. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '378 Patent.

ANSWER: The allegations of Paragraph 96 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs **ADMIT** that there exists an actual controversy between Moderna on the one hand and Plaintiffs on the other hand as to whether the claims of the '378 Patent are valid.

97. Moderna is entitled to a declaration that one or more claims of the '378 Patent are invalid.

ANSWER: Plaintiffs **DENY** the allegations of Paragraph 97.

ATTORNEYS' FEES

98. This is an exceptional case entitling Moderna to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

ANSWER: Plaintiffs **DENY** that Moderna is entitled to an award of attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

99. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Moderna hereby respectfully requests a jury trial on all issues and claims so triable.

ANSWER: Plaintiffs acknowledge that Moderna's Counterclaims purport to set forth a demand for a jury trial on all issues and claims so triable. Paragraph 99 contains conclusions of law to which no response is required. To the extent a response is deemed required, Plaintiffs **DENY** the allegation in Paragraph 99 and **DENY** that Defendants are entitled to any relief whatsoever.

RESPONSE TO PRAYER FOR RELIEF

ANSWER: The "WHEREFORE" paragraphs following Paragraph 18 under the title "ADDITIONAL DEFENSES" set forth the remainder of Moderna's request for relief, to which no response is required. To the extent that a response is required, Plaintiffs **DENY** the allegations in the "WHEREFORE" paragraphs following Paragraph 18 under the title "ADDITIONAL DEFENSES," and **DENY** that Moderna is entitled to its requested relief, or any relief whatsoever.

To the extent that a further answer is required to any paragraph of Moderna's Counterclaims, Plaintiffs deny all further allegations. Any allegation of Moderna's Counterclaims not expressly admitted herein is denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Moderna's counterclaims fail to allege facts sufficient to state a cause of action and fail to state a claim on which relief may be granted.

Plaintiffs reserve the right to assert further affirmative defenses in the event that discovery indicates that such defenses would be appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. An order dismissing each of Moderna's counterclaims, with prejudice, and denying all relief sought by Moderna;

B. A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

C. Costs and expenses in this action; and

D. Such further and other relief as this Court may deem just and proper.

/s/ Nathan R. Hoeschen

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